UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,630	07/19/2001	Ming-Fong Lin	UNMC.63131US	7143

7590 02/24/2005

Stephanie L. Seidman
Heller Ehrman White & McAuliffe LLP
4350 LA Jolla Village Drive
7th Floor
San Diego, CA 92122-1246

EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,630	LIN, MING-FONG	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

NON-FINAL ACTION

1. The applicant's Request for the revival of 09/889,630 (filed 21 DEC 04) has been considered and is found to be persuasive. A non-final office action follows. **Claim(s) 1-32 is/are pending with Claims 1-13 and 22-32** withdrawn from consideration as the result of a restriction requirement (see the Office Action mailed 05 OCT 01). A non-final office action follows. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Please note that this application has been transferred to a different examiner within Art Unit 1634. See the closing paqragraph of this action for details.

35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

3. **Claim(s) 14-21** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. [Cancer Research (1992)] in view of Lin et al. [J. Biological Chemistry (1998)] .

Claim 14 is drawn to a method of diagnosing androgen-insensitive prostate carcinoma comprising the step of determining the expression level of cellular PAcP protein in a prostate carcinoma wherein a decrease in the level of expression of cellular PAcP protein is indicative of the androgen insensitive nature of the carcinoma.

It was well known at the time of the invention that prostate carcinomas show low levels of cellular PacP expression. See for example the abstact of Lin et al. [Cancer Research (1992)]. In addition, Lin et al. (1992) teach measuring the level of cellular PAcP protein in prostate carcinoma i.e. prostate carcinoma cell lines. Furthermore, Lin et al (1992) teach performing Northern blots to detect PAcP expression in these same cell lines. Therefore, it can be said that Lin et al. (1992) teach all of the limitations recited in Claim 14 except these authors do not teach that a decrease in the level of expression of cellular PAcP protein is indicative of the androgen insensitive nature of a prostate carcinoma. However, it was well known in the art at the time of the invention, that prostate carcinomas eventually become androgen–unresponsive (i.e. androgen insensitive) see e.g. Lin et al. (1998) the abstract, lines 4-6. In addition, Lin et al.(1998) teach that the androgen insensitive cell line PC-3 shows no detectable PAcP expression. Finally, these authors also teach that the expression of cellular PAcP correlates with androgen stimulation. See the last lines of the abstract and the last paraqgraph on p.5946. Therefore, absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method(s) disclosed by Lin et al. wherein a decrease in the level of expression of cellular PAcP protein is indicative of the androgen insensitive nature of a prostate carcinoma. The skilled artisan would have been motivated to make this modification in order to detect in patients suffering from prostate carcinoma, those prostate carcinomas that have reach the androgen–unresponsive (i.e. androgen insensitive) phase of their development so that androgen suppression therapy (AST) can be stopped, thereby reducing the risk of the side effects associated with AST in patients who will be unresponsive to said therapy.

Claim 15, is drawn to an embodiment of Claim 14 wherein the step of determining the expression comprises quantifying the concentration of cellular PAcP protein in the prostate carcinoma.

Lin et al. [Cancer Research (1992)] teach this limitation. See, for example, the section of this paper entitled "Materials and Methods" on page 4601. In addition, note that Lin et al. in the J. Biological Chemistry (1998) also teach this limitation. See, for example, the section on p.5940 entitled "Protein Determination," under the section entitled "Experimental Procedures."

Claim 16, is drawn to an embodiment of Claim 15 wherein the cellular PAcP protein is quantified by an antibody immunologically specific to the cellular PAcP protein.

Lin et al. in the J. Biological Chemistry (1998) teach this limitation. See, for example, the section on p.5940 entitled "Western Blot Analysis," under the section entitled "Experimental Procedures."

Claim 17, is drawn to an embodiment of Claim 14 wherein the step of determining the expression comprises quantifying the activity of cellular PAcP in the prostate carcinoma.

Lin et al. [Cancer Research (1992)] teach this limitation. See for example p.4601 in the "Materials and Methods" section. In addition, note that Lin et al. in the J. Biological Chemistry (1998) teach quantifying the activity of cellular PAcP in a prostate carcinoma cell line. See the section on p.5940 entitled "Experimental Procedures."

Claim 18, is drawn to an embodiment of Claim 17 wherein cellular PAcP is quantified by measuring phosphatase activity.

Lin et al. [Cancer Research (1992)] teach this limitation. See for example p.4601 in the "Materials and Methods" section. In addition, Lin et al. in J. Biological Chemistry (1998) teach quantifying the activity of cellular PAcP in a prostate carcinoma cell line by measuring phosphatase activity. See for example the section on p.5940 entitled "Protein Phosphatase Activity Assay," under the section entitled "Experimental Procedures."

Claim 19 is drawn to an embodiment of Claim 14 wherein the step of determning the expression comprises quantifying the concentration of cellular PAcP mRNA of in the prostate carcinoma.

Lin et al. [Cancer Research (1992)] teach this limitation. See for example Figure 5 wherein Northern blot analysis is performed.

Claim 20 is drawn to an embodiment of Claim 19 wherein the cellular PAcP mRNA is quantified by a method selected from a defined group which comprises Northern blotting.

Lin et al. [Cancer Research (1992)] teach this limitation. See, for example, Figure 5 wherein Northern blot analysis is performed. In addition, note that Lin et al. in the J. Biological Chemistry (1998) teach quantifying the cellular PAcP mRNA in a prostate carcinoma cell line using Northern blots, as well as, RT-PCR. See the section on p.5940-5941 entitled "Experimental Procedures."

Claim 21 is drawn to an embodiment of Claim 19 wherein the cellular PAcP mRNA is quantified by its specific hybridization to a nucleic acid sequence selected from a defined group which includes SEQ ID NO: 3 and SEQ ID NO: 4.

Lin et al. in the J. Biological Chemistry (1998) teach quantifying cellular PAcP mRNA by RT-PCR using SEQ ID NO: 3 and SEQ ID NO: 4. See p.5941 of the section entitled "Experimental Procedures."

CONCLUSION

4. **Claim(s) 14-21** is/are rejected and/or objected to for the reason(s) set forth above.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHAN WHISENANT
PRIMARY EXAMINER

Art Unit 1634